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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,699	04/21/2004	Karen M. Cheves	1001.1705101	5388

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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
GILBERT, ANDREW M	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,699	CHEVES ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,15 and 25* is/are pending in the application.

4a) Of the above claim(s) *25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4, 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed 8/10/2007.

2. Claim 25 remains withdrawn

3. Thus, claims 4 and 15 are pending for examination.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al (5320634) in view of Parodi (5250070).

6. In reference to claim 4, Vigil et al discloses a medical device, comprising: an elongate shaft (14) having a proximal end, a distal end, a first lumen (14) extending therethrough, and a second lumen (col 4, lns 63-64) extending therethrough; a balloon (12) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (Fig 3b); and one or more cutting members affixed to the balloon (31), the one or more cutting members each having a longitudinal axis (Figs 3a, 4a-b), wherein the one or more cutting members each include a traction region that is configured to improve traction between the balloon and a target site (Figs 3a, 4a-b; and previous discussion of "traction region" in paragraphs 4-7 of the Final office action

mailed on 11/1/2006). In reference to claim 15, Vigil et al additionally discloses a cutting blade (31) affixed to the balloon (Fig 3a-b, 4a-b), the cutting blade including means for cutting and means for gripping thereon and having a longitudinal axis (Fig 3a-b, 4a-b).

7. However, Vigil et al fails to expressly disclose wherein the cutting member/blade has a traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis.

8. Parodi teaches that it is known to have the traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis (Fig 6c, summary, col 3, lns 2-col 4, lns 11) for the purpose of providing a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, lns 3-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the traction region as taught by Vigil et al with the traction region defined by a series of undulations curving from side to side relative to the longitudinal axis in the cutting members as taught by Parodi for the purpose of a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, lns 3-11).

9. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lary (6306151) in view of Parodi (5250070).

10. In reference to claim 4, Lary discloses a medical device, comprising: an elongate shaft (10) having a proximal end, a distal end, a first lumen (Fig 7) extending

therethrough, and a second lumen (Fig 2) extending therethrough; a balloon (13) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (Fig 6); and one or more cutting members affixed to the balloon (Fig 4, 9), the one or more cutting members each having a longitudinal axis (Fig 4, 9), wherein the one or more cutting members each include a traction region that is configured to improve traction between the balloon and a target site (Fig 4, 9; and previous discussion of "traction region" in paragraphs 4-7 of the Final office action mailed on 11/1/2006), wherein the traction region is defined by a series of undulations in the cutting members (Fig 9). In reference to claim 15, Lary additionally discloses a cutting blade affixed to the balloon (Fig 4, 9), the cutting blade including means for cutting and means for gripping thereon and having a longitudinal axis (Fig 4, 9).

11. However, Lary fails to expressly disclose wherein the cutting member/blade has a traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis.

12. Parodi teaches that it is known to have the traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis (Fig 6c, summary, col 3, lns 2-col 4, lns 11) for the purpose of providing a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, lns 3-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the traction region as taught by Lary. with the traction region defined by a series of undulations curving from side to side relative to the

longitudinal axis in the cutting members as taught by Parodi for the purpose of a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, lns 3-11).

Response to Arguments

13. Applicant's arguments filed 8/10/2007 have been fully considered but they are not persuasive.

14. The Applicant argues that:

i. The Examiner has mischaracterized the art. Parodi teaches a balloon with external surface irregularities. Virgil et al teaches a balloon having cutting members affixed to the balloon. If the external surface irregularities of Parodi are applied to the balloon of Virgil et al or Lary the resultant combination would still fail to teach or suggests the applicant's claimed invention. (Remarks, pg 5, paragraph 1 and pg 6, paragraph 1)

ii. Parodi does not make reference to a cutting member or cutting blade whatsoever and thus has no teaching that the exterior surface irregularities may be utilized on the cutting member or blade. Rather, surface irregularities would be applied to the exterior surface of the balloon of Virgil et al or Lary (Remarks, pg 5, paragraph 2 and pg 6, paragraph 1).

15. In response to the Applicant's arguments (i) and (ii), the Examiner respectfully disagrees with the Applicant's characterization of the prior art of record.

16. First, Parodi teaches radially projecting parts (7; Fig 6c) that undulate and curve from side to side relative to the longitudinal axis. The radially projecting parts are on the exterior surface of the balloon. Parodi teaches that the purpose of the radially projecting parts is so that only the outer surfaces of these radially projecting parts contact the vessel wall. The result is that only 10% of the balloon's external surface contacts the vessel when fully inflated. This decreases the damage produced by the balloon on the endothelium (col 3, lns 26-31). The external surfaces of the radially projecting parts are the only parts of the balloon that contact the vessel wall. At the same time, Parodi teaches that the structure and shape of the radially projecting parts, namely – the outer surfaces of the radially projecting parts that can be formed in various shapes – see Fig 6c that has series of undulations curving from side-to-side relative to the longitudinal axis, function to form a non-skidding surface that admits the dilatation of fibrous injuries producing a smaller dissection of the intima (col 4, lns 8-11). Thus, the shape and structure of the outer surface of the radially projecting parts are disclosed to form a non-skidding improving the traction of the balloon surface in comparison to a balloon with no exterior surface irregularities or to non-disclosed exterior surface irregularities.

17. Second, both Virgil et al and Lary disclose cutting members that abrasively contact vessel walls and have traction regions. The Examiner has given the terms of "traction region" is broadest reasonable interpretation; wherein, Webster's dictionary definition reads that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region (see previous discussion "traction

region" in paragraphs 4-7 of Final office action mailed on 11/1/2006). One of ordinary skill in the art at the time of the invention would recognize the benefit of increasing a the frictional coefficient of the traction region to improve adhering and cutting of the vessel wall at the desired site of treatment while minimizing trauma to other areas of the vessel wall. The exterior surface radially projecting parts of Parodi that form the undulations can be applied to the radially projecting cutting members that are affixed to the balloon wall in Virgil et al and Lary et al because all are directed towards the same concept – contacting the vessel wall exterior to the balloon surface. The incorporation of series of longitudinal curving undulations as taught by Parodi would provide an increased non-skidding abrasive traction area in the cutting members of Virgil et al and Lary and thereby would improve their gripping and cutting ability. Thus, the Examines finds motivation to combine the prior art of record in the manner discussed above. The rejections are maintained.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons